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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,776	02/04/2004	Lane Fielding Smith	3365.2.1	3764

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/771,776

Applicant(s)

SMITH, LANE

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 28 and 29 is/are pending in the application.
4a) Of the above claim(s) 8-15, 19 and 20 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7, 16-18, 28 and 29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

Claim Rejections - 35 USC § 112

Claims 1-7,16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, recitation of "extending substantially homogeneously from within" is indefinite. The metes and bounds of this limitation is not clearly supported or described in the specification. It appears that, in the specification, the features of filaments within the wall is disclosed as being non-homogenous. Clarification and/or amendment to the claim is required.

Claim 3, see rejection to claim 1 supra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Audretsch (4950292).

Audretsch discloses an apparatus for mastopexy with augmentation, the apparatus comprising a vessel of an elastomeric material shaped as an outer covering of predetermined size and form; a filler to maintain a volume of the vessel; a back wall forming a surface for contact with tissue posterior thereto; and a plurality of anchors extending substantially homogeneously from within and outwardly from the back wall of

the vessel a distance selected to stabilize the anatomical position thereof and support gravitational loading thereon. (see column 4, lines 37+ and column 6, lines 31+).

Claim 2, see column 4, lines 35+.

Claim 3, see column 4, lines 37+ and column 6, lines 31+.

Claims 4-8, see column 2, lines 14+ and column 6, lines 31+.

Claim 28 is broader than claim 1.

Claim 29, the anchors of Audretsch are non-elastomeric.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 16, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al (4253201) in view of Cloud (6746458).

Ross et al discloses an apparatus for mastopexy with augmentation, the apparatus comprising a vessel of an elastomeric material shaped as an outer covering of predetermined size and form; a filler to maintain a volume of the vessel; a back wall forming a surface for contact with tissue posterior thereto; and a plurality of anchors extending substantially homogeneously from within and outwardly from the back wall of the vessel a distance selected to stabilize the anatomical position thereof and support gravitational loading thereon. (see column 2, lines 37+). While Ross, et al generally

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discloses the loops to be attached to the back of the chamber, Ross, et al is silent as to the mechanism of the same. Cloud teaches attaching one end of a suture to the implantable device and the suture housing may be embedded within a layer of the device. (See column 6, lines 6+). In view of Cloud, to form the implant of Ross, et al with an integral suture housing and suture embedded in an outer layer of the implant to allow the surgeon quick access and direct placement of the suture to the adjacent tissues would have been obvious to one with ordinary skill in the art.

Claim 2, see column 4, lines 35+.

Claim 3, see column 4, lines 37+ and column 6, lines 31+.

Claims 4-8, see column 2, lines 14+ and column 6, lines 31+.

Claim 16, see sutures of Cloud.

Claim 28 is broader than claim 1.

Claim 29, the sutures of Cloud are non-elastomeric.

Claim Rejections - 35 USC § 103

Claims 1, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ross et al (4253201) in view of Cloud (6746458).

As presented supra, Ross et al discloses an apparatus for mastopexy with augmentation, the apparatus comprising a vessel of an elastomeric material shaped as an outer covering of predetermined size and form; a filler to maintain a volume of the vessel; a back wall forming a surface for contact with tissue posterior thereto; and a plurality of anchors extending substantially homogeneously from within and outwardly


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from the back wall of the vessel a distance selected to stabilize the anatomical position thereof and support gravitational loading thereon. (see column 2, lines 37+). While Ross, et al generally discloses the loops to be attached to the back of the chamber, Ross, et al is silent as to the mechanism of the same. Cloud teaches attaching one end of a suture to the implantable device and the suture housing may be embedded within a layer of the device. (See column 6, lines 6+). In view of Cloud, to form the implant of Ross, et al with an integral suture housing and suture embedded in an outer layer of the implant to allow the surgeon quick access and direct placement of the suture to the adjacent tissues would have been obvious to one with ordinary skill in the art. While each of Ross et al and Cloud remain silent as to specific orientation of the placement of the anchoring means on the device, location of the anchors, if not inherent, at positions, 10 and 2 o'clock and/or 7 and 5 o'clock, to provide support of the device would have been obvious to one skilled in the art based upon routine experimentations.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-THURSDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
May 12, 2005